

REMARKS

Claims 1, 4,5, 13, and 16-18 are amended herein. Claims 1-18 are under consideration.

Claim 1 which is directed to an apparatus for analyzing a physiological liquid is amended to delete language added in the prior amendment, and to add that the test device "is arranged in a first position or a second position" in one of the compartments ". The word "secured " is deleted in favor of the word that was previously present in the claim, namely, "arranged". Support is present in the specification, for example, as follows:

Thus, in the present embodiment, **the first and second positions of the cuvette 14 define positions in which unused and used cuvettes, respectively, are positioned.** Due to the engagement between the bead 28 and one of the notches 30 and 30', it is ensured that cuvettes positioned at other angular positions than the operational position may not shift between the used or unused positions.

Specification at 24, lines 4-11 (emphasis added).

Support may also be found, for example, at page 27, line 8 – page 28, line 4; page 22, lines 11 – 22; page 22, line 34 – page 23, line 17.

Conforming amendments are made to dependent claims 4 and 5.

Claim 11 is amended to add the elements "liquid sample path", "filter" and a "pump" as elements of the apparatus. Support is found in the specification, for example, on page 28, line 28 – page 29, line 23; page 34, lines 1 – 7.

Claim 13 which is directed to a holder adapted to hold a plurality of test devices is amended to recite that “each compartment is adapted to have a test device arranged in a first position or a second position”. It is also amended to add that “wherein the holder having a plurality of test devices therein is capable of being discarded.” Support is found in the specification as noted above for amendments to claim 1, and as follows:

According to this first aspect of the invention, the test device holding the sample is retained in a holder wherein the operator cannot gain access to the sample. **When discarding the test device or test devices, the holder containing test devices is discarded.** In this manner, the operator is not subjected to any hazards by these operations.

Id. at 9, lines 20-26 (emphasis added).

Further examples of support include page 4, lines 26-31; page 10, lines 4-24; and page 12, lines 26-31.

Conforming amendments are made to claims 16 and 17 which depend from claim 13.

Claim 18 which is directed to a method of determining a parameter of a sample of a physiological fluid, has been amended to recite the first and second positions for arranging a test device in a compartment, as discussed above. The method claim is further amended to recite “transferring a test device that is in the first position in the aligned compartment out of the opening in the holder housing and into the sample entry position accessible from the ambience”. The step of loading the sample is amended to recite that the test device is “in the sample entry position” accessible from the ambience. After recitation of the step of determining the parameter

of the sample loaded, the following is added: “transferring the test device that has been used for analysis into the opening in the holder and arranging said test device such that it is in the second position in the compartment aligned with the opening of the holder and inaccessible from the ambience”. In the step of rotating the holder member, an amendment adds that the plurality of test devices in the compartments are rotated “away from the opening of the holder and” inaccessible from the ambience. Support is found in the specification, for example:

In order to provide a cuvette in the sample entry position 14’ illustrated by a cuvette in that position, the motor 16 is activated in order to **move an unused cuvette 14 into an operational position from which the cuvette 14 may be transported out of the casing 6 through an opening 18 therein.** The transfer of the cuvette 14 from within the casing 6 to the sample entry position 14’ is provided by a friction belt 20 engaging the lower side of the cuvette 14 and being driven by a motor 22.

Specification at 22, lines 11-20 (emphasis added).

Further support is noted as follows:

In Fig. 2D, a cross section is shown which illustrates the cassette 4 in engagement with the apparatus 2 and wherein a cuvette 14 has been moved, using the means 16, to the operational position so as to be ready for use. It is seen that the **cuvette 14 is in the operational position in the first position populated only by unused cuvettes.**

Subsequently (Fig. 2E), the **cuvette 14 is transferred from the operational position in the cassette 4 to the sample entry position 14’** by operating the motor 22. The cuvette in position 14’ is now ready for introduction of a sample.

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After having performed the measurement, the cuvette in position 14’ is returned to the cassette 4 by again operating the motor 22 (Figs. 2 F and 2G). In Fig. 2G it may be seen that the used cuvette in the operational position is withdrawn to the second position populated only by used cuvettes.

Id. at 27, lines 7-31(emphasis added).

Further support is present in the specification, for example, at page 27, line 32 – page 28, line 4.

No new matter is added by the present amendments.

New Matter Rejection

The Examiner stated that amendments made to the claims filed April 5, 2007 presented new matter. (Paper No. 20070614 at 2). The Examiner asserted that the previously amended language reciting “each compartment comprising two positions for securing a test device” is not supported by the specification. The Examiner also objected to the term “securing”. The Examiner did acknowledge, however, that “[t]he only referencing to positioning observed by the examiner is that mentioned when describing how the device is intended to operate.” (Id.) The Examiner elaborated, “The cuvettes remain closed off or unexposed to the ambience until each cuvette is rotated to a operational position where an opening exists and when at that position the cuvettes are removed and loaded with a sample and tested therein. After testing, the cuvette 14 is returned via opening back to the compartment in the cassette and the cassette is further rotated to the next compartment and the process is repeated for each compartment/cuvette until all of the cuvettes have been employed to test a respective sample.” (Id. at 2-3).

With regard to claim 18, the Examiner stated that “there is no support for loading the sample in the test device while the test device is in the compartment.” The Examiner also stated that “[c]laim 18 does not adequately describe the method as disclosed in the specification...” (Id. at 3).

Applicants submit that the present amendments overcome the new matter rejection. The language that the Examiner objected to has been deleted, and the language added by amendment is discussed above and the support provided in the specification is indicated.

With regard to the present amendments, Applicants note the presence of not only a first or operational position of the test device, but also a second position as discussed above. Particular note is made as the Examiners' comments cited above from the Action acknowledge a first, i.e., operational position, but not the second position of the test device. As the amended language is amply supported, it is submitted that the rejection has been overcome and that no new matter has been added by the present amendments.

Objection to Claim 11

The Examiner objected to claim 11 in that the liquid sample path and filter are not positively claimed as elements. (Id. at 4). The Examiner indicated that the amendments should reflect that “the sample path and filter are elements linked to the port and chamber”. Applicants have amended claim 11 as requested, and the element

of a “pump” has also been added for further linkage of elements. Withdrawal of the objection is requested.

Anticipation Rejection

Claim 18 is rejected under 35 USC 102(e) as anticipated by Fanning et al. (US Patent 5,965,090) (“Fanning”). (Id. at 4). The Examiner stated that “Fanning et al. disclose sample testing machine for testing samples stored in test cards. The machine has a test sample positioning system for moving a tray containing a plurality of test sample cards and fluid receptacles among various stations in the machine.” (Id. at 4-5). The Examiner appears to argue that all elements of claim 18 are present in the use of Fanning’s sample testing machine.

Applicants respectfully submit that each and every element of amended claim 18 is not disclosed in Fanning. Fanning provides no disclosure of a test device arranged in a first position or a second position in a compartment, in which only the first position permits a test device before it has been used for analysis to be moved into a sample entry position outside of the holder. A test device that has been used for analysis is moved back into the holder and arranged in the second position of the compartment which is inaccessible from the ambience even while the compartment is aligned with the opening in the holder. For this reason alone, the rejection has been obviated.

Fanning allows for the option of “transferr[ing the test cards] to a card disposal system when the reading [at an optical reading station] is complete.” Fanning, Abstract. In present claim 18, on the other hand, the test device is separated from the ambience after sample testing in such a manner that the holder containing a plurality of test devices can be discarded. As stated in the specification:

[T]he holder [is] adapted to substantially separate, from the ambience, any test device held therein loaded with a sample, **thus allowing the holder with the sample-holding test device or devices to be discarded without any substantial risk of contact between an operator and the sample.**

Specification at 12, lines 26-31 (emphasis added).

Present claim 18 recites “discarding the holder”. While Fanning allows for discarding the test device (test card), **nowhere is it mentioned by Fanning that the holder (or carousel) is discarded.**

For this additional reason, the rejection has been overcome.

As is well settled, anticipation requires “identity of invention.” *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984).

For each of the reasons set forth above, no identity of invention is present. Each and every element of claim 18 is not found in Fanning.


Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). “Moreover, it is incumbent upon the Examiner to **identify wherein each and every facet** of the claimed invention is disclosed in the applied reference.” *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference “**by page and line**” upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

The rejection fails to identify where in Fanning each and every element of claim 18 is shown. The Examiner has not identified where in Fanning the aspect of “discarding the holder” is found, yet this claim recitation was present in the claim prior to the present amendments. In the rejection, the Examiner fails to state anything regarding the Fanning disclosure with respect to the “discarding” element of claim 18. The rejection having this deficiency is insufficient as a matter of law to support a conclusion of anticipation, and for this additional reason, the rejection should be withdrawn.

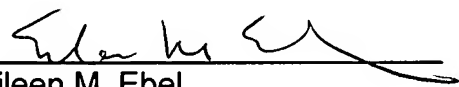
Moreover, there is a “burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103. . . .” *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The rejection fails to provide any basis, let alone the requisite factual basis to sustain a rejection for anticipation. Thus, for this reason also, the rejection should be withdrawn.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being mailed to the United States Patent Office to the Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 on November 19, 2007.


Eileen M. Ebel, Reg. No. 37,316

Respectfully submitted,

By: 
Eileen M. Ebel
Registration No. 37,316
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104
(P) (212) 541-2194
(F) (212) 541-4630